



0590
#3

PATENT
ATTORNEY DOCKET NO. 50010/017003

Certificate of Mailing: Date of Deposit: June 20, 2001

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Susan M. Barry
Printed name of person mailing correspondence

Susan M. Barry
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|-------------|---|---------------|------------------|
| Applicant: | Douglas A. Treco et al. | Art Unit: | Not Yet Assigned |
| Serial No.: | 09/845,020 | Examiner: | Not Yet Assigned |
| Filed: | April 27, 2001 | Customer No.: | 21559 |
| Title: | Genomic Sequences for Protein Production and Delivery | | |

Assistant Commissioner For Patents
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the enclosed Form PTO-1449.

Submission of this statement is not a representation that a search has been made, nor is information included in this statement an admission that the information is material to patentability.

Under 35 U.S.C. § 120, this application relies on the earlier filing date of application serial number 09/305,384, filed on May 5, 1999. The following references were submitted to the Office in the prior application and, therefore, are not provided in this application:

U.S. Patent No. 5,641,670

U.S. Patent No. 5,733,761

WO 95/31560

Arakawa et al., "Structure and Activity of Granulocyte Colony-stimulating Factor Derived From CHO Cells Containing cDNA Coding For Alternatively Spliced Sequences," Archives of Biochemistry and Biophysics 316:285-289 (1995).

Editorial, Nature Biotechnology 15:815 (1997).

Han et al., "Cloning and Expression of the cDNA Encoding Rat Granulocyte Colony-Stimulating Factor," Gene 175:101-104 (1996).

Kershaw et al., "Human DNA Sequence from Cosmid U221F2 on Chromosome X. Contains ESTs and STS," EMBL Database Entry HSU221F2, Accession Number Z75746, XP002110689, Abstract (1996).

Kuczek et al., "A Granulocyte-Colony-Stimulating Factor Gene Promoter Element Responsive to Inflammatory Mediators Is Functionally Distinct from an Identical Sequence in the Granulocyte-Macrophage Colony-Stimulating Factor Gene," The Journal of Immunology 146:2426-2433 (1991).

Kulmburg et al., "Cloning and Sequence Analysis of the Immediate Promoter Region and cDNA of Porcine Granulocyte Colony-stimulating Factor," Gene 197:361-365 (1997).

Leizer et al., "Cytokine Regulation of Colony-Stimulating Factor Production in Cultured Human Synovial Fibroblasts: I. Induction of Gm-CSF and G-CSF Production by Interleukin-1 and Tumor Necrosis Factor," Blood 76:1989-1996 (1990).

Monaco et al., "Expression of Recombinant Human Granulocyte Colony-Stimulating Factor in CHO dhfr Cells: New Insights into the In Vitro Amplification Expression System," Gene 180:145-150 (1996).

Nagata, Granulocyte Colony-Stimulating Factor, In: Peptide Growth Factors and Their Receptors, Sporn and Roberts (eds.), Springer-Verlag New York, NY 699-722 (1991).

Nagata et al., "Molecular Cloning and Expression of cDNA for Human Granulocyte Colony-Stimulating Factor," Nature 319:415-418 (1986).

Nagata et al., "The Chromosomal Gene Structure and Two mRNAs for Human Granulocyte Colony-Stimulating Factor," The EMBO Journal, 5:575-581 (1986).

Nishizawa et al., "Regulatory Elements Responsible for Inducible Expression of the Granulocyte Colony-Stimulating Factor Gene in Macrophages," Molecular and Cellular Biology 10:2002-2011 (1990).

Orkin et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy," National Institutes of Health (1995).

Reidhaar-Olson et al., "Identification of Residues Critical to the Activity of Human Granulocyte Colony-Stimulating Factor," Biochemistry 35:9034-9041 (1996).

Rotondaro et al., "High-level Expression of a cDNA for Human Granulocyte Colony-Stimulating Factor in Chinese Hamster Ovary Cells. Effect of 3'-noncoding Sequences," Molecular Biotechnology 7:231-240 (1997).

Stanley et al., "The Structure and Expression of the Murine Gene Encoding Granulocyte-Macrophage Colony Stimulating Factor: Evidence for Utilisation of Alternative Promoters," The EMBO Journal 4:2569-2573 (1985).

Tweardy et al., "Molecular Cloning and Characterization of a cDNA for Human Granulocyte Colony-Stimulating Factor (G-CSF) from a Glioblastoma Multiforme Cell Line and Localization of the G-CSF Gene to Chromosome Band 17q21," Oncogene Research 1:209-220 (1987).

Tweardy et al., "Molecular Cloning of cDNAs for the Human Granulocyte Colony-Stimulating Factor Receptor from HL-60 and Mapping of the Gene to Chromosome Region 1p32-34," Blood 79:1148-1154 (1992).

Verma et al., "Gene Therapy - Promises, Problems, and Prospects," Nature 389:239-242 (1997).

If there are any charges or any credits, please apply them to Deposit Account

No. 03-2095.

Respectfully submitted,

Date: June 20, 2001

Susan M. Michaud
Susan M. Michaud, Ph.D.
Reg. No. 42,885

Clark & Elbing LLP
176 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045
50010.017003 Information Disclosure Statement.wpd

PATENT TRADEMARK OFFICE



21559



Sheet 1 of 2

| | | | | | | |
|---|---|------------------|--------------------------|---|----------|------------------------------|
| SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (MODIFIED) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. §1.98(b)) | | | | Attorney Docket No. 50010/017003 Serial No. 09/845,020 Applicant Douglas A. Treco et al. Filing Date April 27, 2001 Group Not Yet Assigned IDS Filed June 20, 2001 Customer No. 21559 | | |
| U.S. PATENTS | | | | | | |
| Examiner's Initials | Patent Number | Issue Date | Patentee | Class | Subclass | Filing Date (If Appropriate) |
| | 5,641,670 | 06/24/97 | Treco et al. | 435 | 240.2 | |
| | 5,733,761 | 03/31/98 | Treco et al. | 435 | 172.3 | |
| FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION | | | | | | |
| Examiner's Initials | Document Number | Publication Date | Country or Patent Office | Class | Subclass | Translation (Yes/No) |
| | WO 95/31560 | 11/23/95 | PCT | | | |
| OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) | | | | | | |
| | Arakawa et al., "Structure and Activity of Granulocyte Colony-Stimulating Factor Derived From CHO Cells Containing cDNA Coding For Alternatively Spliced Sequences," Archives of Biochemistry and Biophysics 316:285-289 (1995). | | | | | |
| | Editorial, Nature Biotechnology 15:815 (1997). | | | | | |
| | Han et al., "Cloning and Expression of the cDNA Encoding Rat Granulocyte Colony-Stimulating Factor," Gene 175:101-104 (1996). | | | | | |
| | Kershaw et al., "Human DNA Sequence from Cosmid U221F2 on Chromosome X. Contains ESTs and STS," EMBL Database Entry HSU221F2, Accession Number Z75746, XP002110689, Abstract (1996). | | | | | |
| | Kuczek et al., "A Granulocyte-Colony-Stimulating Factor Gene Promoter Element Responsive to Inflammatory Mediators Is Functionally Distinct from an Identical Sequence in the Granulocyte-Macrophage Colony-Stimulating Factor Gene," The Journal of Immunology 146:2426-2433 (1991). | | | | | |
| | Kulmburg et al., "Cloning and Sequence Analysis of the Immediate Promoter Region and cDNA of Porcine Granulocyte Colony-Stimulating Factor," Gene 197:361-365 (1997). | | | | | |
| | Leizer et al., "Cytokine Regulation of Colony-Stimulating Factor Production in Cultured Human Synovial Fibroblasts: I. Induction of Gm-CSF and G-CSF Production by Interleukin-1 and Tumor Necrosis Factor," Blood 76:1989-1996 (1990). | | | | | |
| | Monaco et al., "Expression of Recombinant Human Granulocyte Colony-Stimulating Factor in CHO dhfr Cells: New Insights into the In Vitro Amplification Expression System," Gene 180:145-150 (1996). | | | | | |
| EXAMINER | | | | DATE CONSIDERED | | |
| EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant. | | | | | | |

Sheet 2 of 2

| | | | |
|---|--|---------------------|-------------------------|
| SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (MODIFIED) PATENT AND TRADEMARK OFFICE | | Attorney Docket No. | 50010/017003 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) | | Serial No. | 09/845,020 |
| | | Applicant | Douglas A. Treco et al. |
| | | Filing Date | April 27, 2001 |
| | | Group | Not Yet Assigned |
| | | IDS Filed | June 20, 2001 |
| (37 C.F.R. §1.98(b)) | Customer No. | 21559 | |
| OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) | | | |
| | Nagata, Granulocyte Colony-Stimulating Factor, In: Peptide Growth Factors and Their Receptors, Sporn and Roberts (eds.), Springer-Verlag New York, NY 699-722 (1991). | | |
| | Nagata et al., "Molecular Cloning and Expression of cDNA for Human Granulocyte Colony-Stimulating Factor," Nature 319:415-418 (1986). | | |
| | Nagata et al., "The Chromosomal Gene Structure and Two mRNAs for Human Granulocyte Colony-Stimulating Factor," The EMBO Journal, 5:575-581 (1986). | | |
| | Nishizawa et al., "Regulatory Elements Responsible for Inducible Expression of the Granulocyte Colony-Stimulating Factor Gene in Macrophages," Molecular and Cellular Biology 10:2002-2011 (1990). | | |
| | Orkin et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy," National Institutes of Health (1995). | | |
| | Reidhaar-Olson et al., "Identification of Residues Critical to the Activity of Human Granulocyte Colony-Stimulating Factor," Biochemistry 35:9034-9041 (1996). | | |
| | Rotondaro et al., "High-level Expression of a cDNA for Human Granulocyte Colony-Stimulating Factor in Chinese Hamster Ovary Cells. Effect of 3'-noncoding Sequences," Molecular Biotechnology 7:231-240 (1997). | | |
| | Stanley et al., "The Structure and Expression of the Murine Gene Encoding Granulocyte-Macrophage Colony Stimulating Factor: Evidence for Utilisation of Alternative Promoters," The EMBO Journal 4:2569-2573 (1985). | | |
| | Tweardy et al., "Molecular Cloning and Characterization of a cDNA for Human Granulocyte Colony-Stimulating Factor (G-CSF) from a Glioblastoma Multiforme Cell Line and Localization of the G-CSF Gene to Chromosome Band 17q21," Oncogene Research 1:209-220 (1987). | | |
| | Tweardy et al., "Molecular Cloning of cDNAs for the Human Granulocyte Colony-Stimulating Factor Receptor from HL-60 and Mapping of the Gene to Chromosome Region 1p32-34," Blood 79:1148-1154 (1992). | | |
| | Verma et al., "Gene Therapy - Promises, Problems, and Prospects," Nature 389:239-242 (1997). | | |
| EXAMINER | | DATE CONSIDERED | |
| EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant. | | | |